August 22, 2019

BioBeat Technologies Ltd.
% Yarmela Pavlovic
Partner
Hogan Lovells US LPP
3 Embarcadero Center, Suite 1500
San Francisco, California 94111

Re: K190792
Trade/Device Name: BB-613 WP
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, DRG
Dated: July 19, 2019
Received: July 19, 2019

Dear Yarmela Pavlovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 *See PRA Statement on last page*

510(k) Number *(if known)*

K190792

Device Name

BB-613 WP

Indications for Use *(Describe)*

The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate.

The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO_2 sensor, following a calibration process using oscillometric blood pressure monitor.

The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K190792

510(k) SUMMARY

Biobeat Technologies Ltd.'s BB-613 WP

Submitter:

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Date Prepared: August 19, 2019

Name of Device: BB-613 WP

Common or Usual Name: Oximeter, non-invasive blood pressure measurement system

Classification Name: 21 C.F.R. 870.2700 Oximeter, 870.1130 Noninvasive blood pressure measurement system

Regulatory Class: Class II
Product Code: DQA, DXN, DRG

Primary Predicate Devices: K181006 BB-613

Secondary Predicate Devices:

K113165 Mini-Medic
K173028 BPro BP Ambulatory Blood Pressure Monitoring System
K163255 Caretaker4 Physiological Monitor

Device Description:

The BB-613WP consists of a light source (LEDs) and sensor array on the backside of the device. The device is available in two versions, a watch version and an adhesive patch version. The LEDs transmit light into the subject's skin and part of this light is reflected from the tissue and detected by a photo-diode. The integrated display is used to display the blood saturation, pulse rate results and changes in blood pressure following calibration. These results are displayed on the LCD screen for the watch version and/or displayed on a mobile application installed on the user's phone. The display also shows symbols that show if there was no signal or a weak signal as well as battery status.

Intended Use / Indications for Use:

The BB-613WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate.

The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO_2 sensor, following a calibration process using oscillometric blood pressure monitor.

The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

Summary of Technological Characteristics:

The watch model of the subject device and the predicate device are identical in regards to physical components and differ only in regards to software (the addition of the blood pressure algorithm and Bluetooth connectivity, which is discussed below).

The subject patch model uses the same sensor unit and SpO_2 and pulse rate algorithms as the predicate. The primary difference, beyond calculation of blood pressure parameters and Bluetooth connectivity, between the subject and predicate devices is the inclusion of the adhesive patch form factor. The adhesive patch model primarily differs from the predicate BB613 in regards to method used to attach the device to the patient and the user interface. Specifically, the predicate attaches to the patient with a watch band whereas the subject device additionally uses an adhesive patch. Differences in attachment method do not raise new types of questions and the effectiveness of the adhesive patch to maintain good contact with the patient over its intended use life has been demonstrated.

The user interface has also been modified. Both devices perform a spot check only after the user presses a button to begin measurement, although the design location of the button differs. The predicate device contains an integrated LCD screen used to display the results of the measurement. In the subject device, the user installs an app on their smart phone that allows the device to wirelessly transmit the results to the smartphone. However, aside for the addition of date and time, the same information is displayed to the user. The subject device also differs from the predicate in that information is transmitted wirelessly through Bluetooth. While the predicate BB613 physically contains the Bluetooth array, this feature was not activated. The BB-613WP and the Mini-Medic (K113165) predicate device both use Bluetooth components to transmit the data to a handheld device.

Both the subject and the predicate devices have the same contact classification and duration, permanent contact device with intact skin. All devices are supplied and used non-sterile. All devices use software to control the device and analyze and display the results. The new software elements have been documented and validated per FDA guidance. All devices contain electronics that present electrical hazard and EMC risks. As the electronic components are identical to the predicate, repeated safety testing was needed. EMC testing unique to the activated Bluetooth feature of the device were performed. In sum, although there are minor differences in the

technological characteristics, these differences do not raise difference questions and the provided testing establishes equivalent performance as compared to the predicates.

The primary difference between the subject and primary predicate devices is the inclusion of blood pressure measurement via PWTT. However, the same underlying principle of PWTT is found in BPro BP Ambulatory Blood Pressure Monitoring System (K173028) as well as Mini-Medic (K113165), although the details of how PWTT is measured slightly differs between the devices.

Specifically, the subject device determines the PWTT optically, while the reference device measures PWTT via ECG or tonometry. Differences in measurement method do not raise different questions of safety or efficacy as both are measuring the same underlying physical phenomenon. Further, Caretaker4 Physiological Monitor K163255) also measures blood pressure optically, although they measure rise time of the pulse wave as an indirect measure of PWTT, while the subject device measures it directly. Ultimately, the critical question for all of these devices is whether the device produces as accurate measurement of change in blood pressure based on PWTT. The company has performed pre-clinical and clinical testing to validate the measured change in blood pressure per ISO 80601-2-61:2011.

Summary of Comparison to Predicate Devices:

Device	**Subject Device BB-613WP**	**Primary Predicate Device BB-613 (K181006)**	**Secondary Predicate Device Mini-Medic (K113165)**
Indications	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin ($\%SpO_2$) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO_2 sensor, following a calibration process using oscillometric blood pressure monitor.	The BB-613 Watch Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin ($\%SpO_2$) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.	The mini-Medic™ system is comprised of a minimum of one Forehead Sensor Unit and one Handheld Display Unit and is intended for use on patients who are eighteen (18) years and over. The mini-Medic™ system is indicated as a single or multi-parameter vital signs monitor for SpO_2 and pulse rate via an integrated SpO_2 forehead sensor, and/or heart rate from ECG electrodes, and forehead skin surface temperature from an infrared temperature sensor. Pulse wave transit time (PWTT) is obtained utilizing pulse measurements from

Device	Subject Device BB-613WP	Primary Predicate Device BB-613 (K181006)	Secondary Predicate Device Mini-Medic (K113165)
	The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.		the integrated SpO_2 forehead sensor and ECG electrodes placed on the upper chest. Pulse wave transit time (PWTT) is used to track changes in blood pressure. Skin temperature is used as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature for hyperthermia and hypothermia conditions. Patient data may be entered on the Handheld Display Unit. The mini-Medic™ system provides vital parameter alarms and a patient composite/summary alarm. Patient information and system commands are transmitted using wireless radio communications between the Forehead Sensor Unit and the Handheld Display Unit. Stored patient data may be output, printed, downloaded and saved via a dedicated mini-Medic™ PC Software application. Typical locations for the use of the mini-Medic™ system are: pre-hospital (i.e., at the point of injury or trauma scene), hospital, healthcare facility, emergency medical application, and during ground or air transport. The

Device	Subject Device BB-613WP	Primary Predicate Device BB-613 (K181006)	Secondary Predicate Device Mini-Medic (K113165)
			monitor is intended to be used by trained healthcare providers in military and civilian roles including doctors, nurses, combat medics, combat lifesavers, EMT's, and paramedics.
Use Population	Adults	Adults	Adults
Use Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	Pre-hospital (i.e., at the point of injury or trauma scene), hospital, healthcare facility, emergency medical application, and during ground or air transport.
Monitoring	Spot-checking	Spot-checking	Spot-checking
Principle of Operation	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attached SpO_2 sensor	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light	Integrated SpO_2 forehead sensor, and/or heart rate from ECG electrodes, and forehead skin surface temperature from an infrared temperature sensor and pulse wave transit time (PWTT) to track changes in blood pressure
Measurement site	Wrist area and skin	Wrist area and skin	Forehead sensor and handheld display unit
Measurement type	Spot	Spot	Spot
Emitted light peak wavelength	880nm (IR), 650nm (Red)	880nm (IR), 650nm (Red)	Unknown
Measurement Range SpO_2	40% to 99%	40% to 99%	Unknown
$A_{rms,}$ SpO_2	±2%	±2%	Unknown

Device	Subject Device BB-613WP	Primary Predicate Device BB-613 (K181006)	Secondary Predicate Device Mini-Medic (K113165)
Measurement Range, HR	40 to 250 bpm	40 to 250 bpm	Unknown
$A_{rms,}$ HR	±3%	±3%	Unknown
Measurement Range, BP	0 mmHg – 299 mmHg	NA	Unknown
Accuracy blood pressure	±5 mmHg	NA	±3 mmHg
Contact material	Polycarbonate, photodiode window, silicone, adhesive patch	Polycarbonate, photodiode window, silicone	Unknown
Application Method	User wears the device as a watch and powers it on or the device is attached to the skin using biocompatible adhesive patch	User wears the device as a watch and powers it on	Multiple chest, ECG electrode and pulse oximetry measured from the forehead
Sterility	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile
Data display	LCD on device or handheld display unit (e.g. mobile phone)	LCD on device	Handheld display
Data storage	No but can transmit the data to handheld device	No	Transmit the data to handheld device

Performance Data:

Performance Data - Bench Tests

The watch model of the BB-613WP uses the same hardware as the cleared BB-613 aside for software changes. The device contains the same sensor unit and uses the same algorithm to compute SpO_2 and pulse rate. Therefore, the SpO_2 and pulse rate testing submitted in K181006 remains applicable to both models of the subject device.

The following bench tests were performed:

- Software validation per FDA guidance
- EMC testing per IEC 60601-1-2:2014
- Cytotoxicity, sensitization and irritation per ISO 10993

Performance Data - Animal Tests

In order to demonstrate substantial equivalence to the reference device, an animal study that evaluate the efficacy of the BB-613WP to detect blood pressure an animal model study was performed.

The study results present the reliability and validity of a photoplethysmograph device (BB-613WP, BioBeat Ltd.) and comparing it to the gold standard device including systolic and diastolic blood pressure which were measured in a swine model.

Performance Data - Clinical Tests

Clinical validations of blood pressure per ISO 80601-2:2013 were performed.

When comparing BP measurements of reference devices to the BB-613WP device, it was showed that the BB-613WP achieved the requirements of the ISO 81060-2:2013 and accurately displayed blood pressure. In terms of safety, during the studies, there were no safety events, showing the BB-613WP to be a safe device for use.

Conclusions

The BB-613WP is as safe and effective as the predicate devices. The BB-613 WP has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the BB-613WP and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the BB-613WP is as safe and effective. Thus, the BB-613WP is substantially equivalent.